NOV - 1 2000

510(K) SUMMARY

FOI RELEASABLE

Persuant to § 513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Medovations, Inc. is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Medovations, Inc. chooses to submit a summary of information respecting safety and effectiveness.

Common/Usual Name:	Balloon Dilatation Catheter, Disposable
Proprietary Name:	TBD
Classification Name and Device Classification:	Class II

Name	Number	21 CFR Ref.
Dilator, Esophageal	78 KNQ	§ 876.5365

Owner/Operator:	MEDOVATIONS, INC. 102 East Keefe Avenue Milwaukee, Wisconsin 53212 USA
Contact Person:	William Elesh, VP, Quality Assurance

DESCRIPTION OF DEVICE

The Medovations Balloon Dilatation Catheter is a single size, single lumen, fixed wire balloon dilator.

INDICATIONS FOR USE

The Medovations Balloon Dilatation Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Medovations, Inc. believes that the Medovations Balloon Dilatation Catheter is substantially equivalent to the currently-marketed Microvasive Achiever™ as well as the Microvasive CRE™ Esophageal Catheter. The major components of the Medovations Balloon Dilatation Catheter are the hub, catheter shaft, stylet wire and the balloon. A thorough comparison of the descriptive characteristics between the Medovations Balloon Dilatation Catheter and the predicate devices show equivalence.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on the Medovations Balloon Dilatation Catheter to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the Medovations Balloon Dilatation Catheter with satisfactory results.

CONCLUSION

Medovations, Inc. believes that the Medovations Balloon Dilatation Catheter is substantially equivalent to the currently marketed MicroVasive Achiever™, the CRE™ and other Esophageal Catheters. A comparison of the descriptive characteristics of these products demonstrate the Medovations Balloon Dilatation Catheter is equivalent in its indications for use, while being very similar in design and materials. In addition, Medovations, Inc. has presented laboratory testing and biocompatibility information. The information presented provides assurance that the Medovations Balloon Dilatation Catheter will meet the minimum requirements that are considered acceptable for its intended use.

Blns&el

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2000

Medovations, Inc.
c/o Mr. Michael J. Brown
Director, Medical Products
Murray, Inc.
1294 Barclay Blvd.
BUFFALO GROVE IL 60089

Re: K002363
Medovations Esophageal Dilator
Dated: August 2, 2000
Received: August 3, 2000
Regulatory Class: II
21 CFR §876.5365/Procode: 78 KNQ

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indication For Use

510(k) Number: K002363

Device Name: MEDOVATIONS ESOPHAGEAL DILATOR

Indications For Use:

The MEDOVATIONS BALLOON DILATATION CATHETER is intended for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002363

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)